REMARKS

This paper is filed in response to the Office Action dated August 22, 2007. Claims 13-15 are pending. Claims 1-12 and 16-23 are withdrawn.

The Examiner's formal objections to the specification have been corrected herein.

Claim 13 has been amended herein to specify that the compounds of the present invention inhibit mycobacterial serine/threonine protein kinase G (PknG). Support for the amendment can be found throughout the specification, *see, e.g.*, page 5, lines 11-15.

Response to issues presented under 35 U.S.C. §112, first paragraph

In the Office Action, the Examiner rejects Claims 13-15 under 35 U.S.C. §112, first paragraph, as not being enabled by the specification in such a way to allow a person skilled in the art to make and use invention as claimed. Specifically, the Examiner contends:

> "The specification, while being sufficiently enabling for inhibitors of *M. tuberculosis*, *M. smegmatis*, and *M. bovis* serine/threonine kinases, does not reasonably provide enablement for the extremely broad scope of inhibitors of any/all serine/threonine kinases or any/all other species of mycobacteria." (Office Action, page 4)

Applicants disagree. It is incumbent on the Examiner in rejecting claims under the first paragraph of 35 U.S.C. §112 to establish a *prima facie* case of lack of enablement. *In re Strahilevitz*, 668 F.2d 1229, 1232; 212 USPQ 561, 563 (CCPA 1982). In determining whether or not a disclosure is enabling, it has been consistently held that the enablement requirement of 35 U.S.C. §112, first paragraph, requires nothing more than objective enablement, *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971); and in meeting the enablement requirement, an applicant's specification need not teach, and preferably omits, that which is well-known in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

How the enabling teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance, since the specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of 35 U.S.C. §112 unless there is a reason to doubt the objective truth of the statements relied upon for enabling support. *In re Marzocchi*, 439 F.2d at 223, 169 USPQ at 369 (CCPA 1971).

With respect to the Examiner's argument that the claimed methods may include inoperative embodiments, *i.e.*, the assertion that the compounds of the present invention may not effectively inhibit

particular mycobacterial serine/threonine protein kinases, Applicant points out that it is not the function of the claims to specifically exclude all possible inoperative embodiments. *Atlas Powder Co. v. E.I. Du Pont de Nermous & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 414 (Fed. Cir. 1984). Moreover, Applicants provide sufficient teaching to those skilled in the art to identify and screen for further compounds and/or serine/threonine protein kinases, *e.g.*, see Examples 1-3 of the specification.

Applicants submit that the claims are fully enabled by the teachings of the application; however, in an effort to advance the prosecution of the application, and in no way acquiescing to the reasoning of the Examiner, Applicants have amended Claims 13-15 herein to specify that the compounds of the invention are inhibitors of mycobacterial serine/threonine protein kinase G (PknG).

In view of the foregoing remarks and amendments herein, reconsideration and removal of the rejection of Claims 13-15 under 35 U.S.C. §112, first paragraph is requested.

Response to issues presented under 35 U.S.C. §112, second paragraph

In the Office Action, the Examiner rejects Claims 14 and 15 as indefinite, stating that the claims fail to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner specifically objects to the claim term "pharmaceutical" as indefinite, stating:

> "While the definition of "pharmaceutical" is broad, it is not so broad to cover any use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered." (Office Action, page 4)

However, the Examiner then confuses the issue by discussing the *enablement* of the claims, stating:

> "The instant specification does not teach how to use the composition, without due experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a mycobacterial disease in a host to which the substance is administered." (Office Action, page 4)

Applicants disagree that the claims are indefinite (or non-enabled). The definiteness inquiry focuses on whether *those skilled in the art* would understand the scope of the claim *when the claim is read in light of the rest of the specification.* MPEP §2173.02; *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ 2d 1081, 1088 (1986) (emphasis added). Furthermore,

> "[T]he definiteness of the language must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular

> application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore,* 439 F.2d 1235, 169 USPQ 236 (CCPA 1971).

The court in *In re Moore* further elucidated the above rule of law in a footnote, stating:

> "It is important here to understand that under this analysis claims which on first reading--in a vacuum, if you will--appear indefinite may *upon a reading of the specification disclosure* or prior art teachings become quite definite." *Moore,* 439 F.2d at 1235, 169 USPQ at 238 (emphasis added).

Regarding the definiteness of the claim term "pharmaceutical", applicants note that it is a commonly used term in the art and is fully understood by persons skilled in the art. Both the specification, the knowledge of those skilled in the art, and the Examiner's own dictionary citation make it quite clear that there is no lack of clarity in the term pharmaceutical. Applicants submit that Claims 13-15 as written, particularly when viewed in light of the specification, clearly apprise one skilled in the art of their scope and, thereby, serve the notice function required by 35 U.S.C. §112, second paragraph. Nothing more is required of Claims 13-15 under 35 U.S.C. §112, second paragraph.

However, it appears from the Office Action that what the Examiner actually contends is that the claimed pharmaceutical compositions are not enabled by the specification in such a way to allow a person skilled in the art to make and use the invention as claimed.

The main thrust of the Examiner's comments appears to be his concern that the claimed pharmaceutical compositions may not be *efficacious* in fully preventing or curing a mycobacterial infection. Although that is a legitimate concern for other agencies, it is misplaced here. As the CAFC has stated:

> "The Commissioner, as did the Board, confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human [use]. Simply stated, approval of the Food and Drug Administration is not a prerequisite for finding a [treatment] useful within the meaning of 35 U.S.C. §112, first paragraph. Only objective enablement is required." *In re Brana*, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995).

Applicants have identified therapeutic targets for treating mycobacterial infection, *e.g.*, mycobacterium serine/threonine protein kinase G (PknG), validated the target as an effective therapeutic target, *see, e.g.*, Example 2, entitled "Validation of Mycobacterial Kinase as a Mycobacterial Virulence

Gene", and Figures 1-2, screened for inhibitors of the activity of the target kinase, *see*, Example 3, and then tested the ability of the claimed compositions to reduce the persistence and enhanced survival of pathogenic mycobacteria, *see*, Example 4 and Figure 2.

Furthermore, the specification provides ample teaching to those skilled in the art as methods of preparing a pharmaceutical composition of the claimed PknG inhibitors. For example, *see* pages 43-47.

Accordingly, in view of the foregoing remarks and amendments herein, Applicants submit that Claims 13-15 are definite and enabled and fully comply with the requirements of 35 U.S.C. §112, first and second paragraph. Reconsideration and allowance of Claims 13-15 are requested.

Respectfully submitted,

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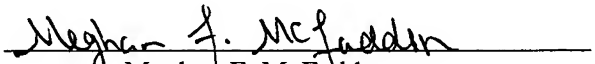

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